

EXHIBIT 24

EXPERT REPORT

**Analysis of Distributor and Manufacturer
Regulatory Compliance to Maintain
Effective Controls for the Prevention of
Diversion of Controlled Substances**

Prepared by

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D. ARCOS/DADS

The Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)¹⁸ system is used to track and report the transfer of pharmaceuticals and to detect potential diversion. This system of records is maintained pursuant to the reporting requirements of the Comprehensive Drug Abuse Prevention and Control Act of 1970¹⁹ and to fulfill the United States treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances of 1971.²⁰

The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispenser level.²¹

The information contained in the ARCOS system consists of documentation of individual business transactions between individuals who handle controlled substances at every level, from manufacturers down to the pharmacies. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, sales, and purchase orders, and includes, but not limited to the date of the transaction, the name, quantity, and quality of the chemicals/substances purchased or dispensed, the parties to the transaction, NCD code, and the DEA registrant numbers. This information provides an audit trail of all manufactured and/or imported controlled substances.

All automated data files associated with ARCOS/DADS are maintained in the Department of Justice Data Center and the Drug Enforcement Administration Data Center and the system is

¹⁸ “ARCOS” refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.) by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. *See* United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, Automation of Reports and Consolidated Orders System (ARCOS), *Background: What is ARCOS and What Does it Do?*, <https://www.deadiversion.usdoj.gov/arcos/#background> (last visited September 7, 2017)

¹⁹ (21 U.S.C. 826(d))

²⁰ 69 FR 51104-02.

²¹ *See* ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, *ARCOS Defined* (Version 1.0 August 1997).

located at Drug Enforcement Administration, 700 Army Navy Drive, Arlington, VA 22202. 69 FR 51104-02.

The ARCOS/DADS system uniquely has access to *all* of the data submitted by each DEA registrant from the across the country.²² These distribution transactional records are compiled by the DEA through a portal and the data is compiled by DEA in accordance with law for determining quota, distribution trends, internal audits, inspection, investigations and other analyses.²³ Additionally, the DEA provides internet access to summary data from this system.

The DOJ/DEA disclosed the national ARCOS database to the Plaintiffs' Executive Committee (2006-2014) and that additional transactional data was independently disclosed by some of the defendants. Both sets of data were then uploaded to a database managed by Craig J. McCann, PhD, CF, of Securities Litigation and Consulting Group, Inc. ("SLCG") (retained as an expert by the PEC). I have relied upon data derived from and provided by SLCG in the formulating of specific requests.

The ARCOS data, defendant transactional data, and the SLCG reports generated therefrom are consistent with the types of data, facts, information, and reports I would typically rely on in conducting the analysis and reaching the opinions contained herein. I am very familiar with the ARCOS data and defendant transactional data and have experience analyzing the data and reports generated therefrom. I have reviewed SLCG's methods and reports and they are consistent with my understanding, based on my experience, of how the data should be analyzed.

E. DEA DIVERSION INVESTIGATOR'S MANUAL.

The DEA published a manual which provides further guidance related to the statutory and regulatory duties. Portions of the manual have previously been publicly available and accurately set forth the charge for DEA investigator as follows:

Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824. Suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern. ***The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted.*** An

²² The DEA maintains the Automation of Reports and Consolidated Orders System ("ARCOS"), an official automated comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial channels to the point of sale or distribution at the dispensing/retail level. Drug wholesalers do not have access to the ARCOS data or to the data of other wholesalers and distributors. *Keysource Med., Inc. v. Holder*, No. 1:11-CV-393, 2011 WL 3608097, at *2 (S.D. Ohio Aug. 16, 2011).

²³ https://www.deaiversion.usdoj.gov/arcos/retail_drug_summary/index.html

respect to the SOMs policies at Insys. However, Mr. Reimer's deposition has been stayed until after the criminal trial by the DOJ in the District of Massachusetts because Mr. Reimer is on the DOJ's witness list.

4. Nevertheless, deposition testimony by current Insys employees has confirmed that Insys failed to implement any SOM system or maintain any SOM protocols until 2018.⁹⁰⁸
5. This failure to conduct any sort of SOM process continued despite the fact that Insys was conscious that it habitually lost track of inventory in its downstream customers like Linden Care.⁹⁰⁹ For other wholesalers where they did not receive inventory level reports, Insys estimated the levels. Significant differences between actual and estimated inventory levels often resulted. Many times, distributor purchases exceeded customer demand, a situation that creates a risk of diversion.

In my expert opinion, Insys failed to conduct any SOM process, even failing to track for orders of unusual size. The lack of any SOM program did not satisfy DEA requirements to detect and investigate suspicious orders. Insys failed to maintain effective controls to prevent diversion.

I reserve the right to amend or supplement my opinions in this matter considering any new or additional information.



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⁹⁰⁸ See Deposition of James Doroz at 53; 118; 251. See also Thomas Udicious Tr. at 19; 44.

⁹⁰⁹ See James Doroz Tr. at 221.